UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., TEVA PHARMACEUTICALS USA, INC., NORTON (WATERFORD) LTD. Plaintiffs, v. DEVA HOLDING A.S. (a/k/a DEVA HOLDINGS A.S.), Defendant.	**Civil Action No. 24-4404 (SRC)** **OPINION & ORDER**

CHESLER, U.S.D.J.

This matter comes before the Court on the motion to dismiss, pursuant to Federal Rule of Civil Procedure 12(b)(1), by Defendant Deva Holding A.S. ("Deva"). The motion has been opposed by Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Teva Pharmaceuticals USA, Inc., and Norton (Waterford) Ltd. (collectively, "Teva"). This Court Ordered supplementary briefing on the subject of the meaning of the word "drug" in the context of 35 U.S.C. § 271(e)(2). For the reasons that follow, the motion will be denied in part and decision will be reserved in part.

On March 29, 2024, Teva filed the Complaint that initiated this case, which asserts eighteen claims of patent infringement. Teva holds the NDA for ProAir® HFA (albuterol sulfate) Inhalation Aerosol. Deva has submitted ANDA No. 21-3818 to market a generic version of this pharmaceutical product. Nine patents have been listed in the Orange Book in connection with Teva's albuterol sulfate inhalation aerosol product. Deva filed a Paragraph IV

certification with respect to each of the nine patents. Teva's Complaint asserts two counts of patent infringement for each of the nine patents, one for infringement under 35 U.S.C. § 271(e)(2), and one for declaratory judgment of infringement, predicated on the expected future marketing of Deva's generic product.

Deva now moves to dismiss the Complaint in its entirety for lack of subject matter jurisdiction, based on two arguments. As to the claims for infringement under 35 U.S.C. § 271(e)(2), Deva argues that none of the nine patents claims a drug and thus there has been no act of infringement under that statutory provision. As to the declaratory judgment claims, Deva argues that the Complaint does not allege sufficient immediacy to trigger declaratory judgment jurisdiction.

As to the declaratory judgment claims, Deva relies on the Federal Circuit's decision in Glaxo, which, Deva contends, requires the allegation of immediacy to support the exercise of declaratory judgment jurisdiction. Deva argues that the Complaint does not allege facts which make plausible an inference of the requisite immediacy; in brief, Deva views the Complaint as alleging no more than a vague possibility that, at some unknown future point in time, the FDA may approve Deva's ANDA and Deva may begin to market an infringing product. Teva opposes the motion, contending that Deva, in short, is wrong on the law.

In the 1997 decision in Glaxo, the Federal Circuit stated:

> The requirement that there be an actual controversy "is met by a sufficient allegation of immediacy and reality." *Lang*, 895 F.2d sat 764, 13 U.S.P.Q.2D (BNA) at 1822. Accordingly, when a patentee seeks a declaratory judgment against an alleged future infringer, the patentee must demonstrate that two elements are present:
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> > (1) the defendant must be engaged in an activity directed toward . . . an infringement charge . . . or be making meaningful preparation for such

> activity; and (2) acts of the defendant must indicate a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming.
>
> *Id.*
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> Under this standard, the district court properly exercised its jurisdiction to consider Glaxo's declaratory judgment claim. Glaxo's complaint was based in part on a letter dated June 8, 1994, in which Novopharm asserted that it intended to market its Form 1 RHCl product after December 5, 1995 (the then expiration date of the '658 patent) but before the expiration of the '431 patent. Novopharm also indicated that it had submitted an ANDA accompanied by data sufficient to make FDA approval imminent. Thus, unlike *Telectronics*, in which we affirmed the dismissal of a declaratory judgment for lack of jurisdiction, the threat of Novopharm entering the U.S. market was not "years away" nor was there doubt that Novopharm wished to sell some form of RHCl. Rather, Novopharm was systematically attempting to meet the applicable regulatory requirements while preparing to import its product.

Glaxo Inc. v. Novopharm Ltd., 110 F.3d 1562, 1571 (Fed. Cir. 1997) (citation omitted). Teva contends that, in the instant case, the Complaint sufficiently alleges facts to demonstrate that the two required elements are present: the Complaint alleges that the defendant has made meaningful preparation for infringing activity (by filing the ANDA), and alleges facts which make plausible the inference that Deva refuses to change the course of its actions in the face of litigation.

Since Glaxo was decided in 1997, the Supreme Court relaxed the legal standard for the exercise of declaratory judgment jurisdiction in MedImmune.[1] The Court summarized the

[1] Neither party, in this briefing, discussed the impact of MedImmune on the vitality of Glaxo. In MedImmune, the Supreme Court reversed a Federal Circuit decision on declaratory judgment jurisdiction. The Federal Circuit subsequently made clear that MedImmune changed the law in that general area:

> Intentionally or not, *MedImmune* may have lowered the bar for determining declaratory judgment jurisdiction in all patent cases; certainly it did so in the licensor-licensee context. *See, e.g., Micron Tech., Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897, 902 (Fed. Cir. 2008) ("[T]he now more lenient legal standard facilitates or enhances the availability of declaratory judgment jurisdiction in patent cases.")

standard for finding a case or controversy sufficient to invoke declaratory judgment jurisdiction as follows:

> Our decisions have required that the dispute be "definite and concrete, touching the legal relations of parties having adverse legal interests"; and that it be "real and substantial" and "admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts" . . . "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."

MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007) (citation omitted). The Court emphasized the importance of entrusting the jurisdictional decision to the discretion of the district court:

> The Declaratory Judgment Act provides that a court "*may* declare the rights and other legal relations of any interested party," 28 U.S.C. § 2201(a) (emphasis added), not that it *must* do so. This text has long been understood "to confer on federal courts unique and substantial discretion in deciding whether to declare the rights of litigants." We have found it "more consistent with the statute," however, "to vest district courts with discretion in the first instance, because facts bearing on the usefulness of the declaratory judgment remedy, and the fitness of the case for resolution, are peculiarly within their grasp."

Id. at 136 (citations omitted). This Court applies the principles set forth in MedImmune to the issues presently before it, and finds that the Complaint alleges sufficient facts to support the finding that there is a definite and concrete infringement dispute between parties with adverse legal interests, which is real and substantial, and which could be resolved by the issuance of a declaratory judgment. Furthermore, the Complaint alleges sufficient facts to support the

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Hewlett-Packard Co. v. Acceleron LLC, 587 F.3d 1358, 1361-62 (Fed. Cir. 2009). In Micron, the Federal Circuit expressly stated that MedImmune enhanced the availability of declaratory judgment jurisdiction in patent cases.

findings that the case is fit for resolution and that a declaratory judgment remedy is useful for resolving this dispute. This Court thus exercises its discretion under MedImmune to decide whether to declare the rights of the litigants before it, and has decided that the requirements for the exercise of declaratory judgment jurisdiction have been met.

The Court observes that MedImmune provides no formula for determining whether the controversy alleged has sufficient immediacy to warrant the issuance of a declaratory judgment.[2] Instead, the Supreme Court directed district courts to consider the usefulness of the declaratory judgment remedy and the fitness of the case for resolution, when deciding to exercise discretion to declare the rights of litigants. This Court concludes that the Complaint alleges a sufficiently real and substantial controversy between the parties to warrant the issuance of a declaratory judgment.

Moreover, shortly after the Supreme Court issued the MedImmune decision, the Federal Circuit acknowledged MedImmune's impact on its declaratory judgment jurisprudence and held:

> A justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents. The combination of these three circumstances is dispositive in establishing an actual declaratory judgment controversy as to all the paragraph IV certified patents, whether the patentee has sued on all or only some of the paragraph IV certified patents.

Teva Pharms. USA, Inc. v. Novartis Pharms. Corp., 482 F.3d 1330, 1344 (Fed. Cir. 2007). In this case, it is more than apparent that Teva, having initiated the Hatch-Waxman infringement

[2] Deva's arguments imply that immediacy, in this case, is somehow tied to the date of FDA approval of its ANDA, which is unknown. In MedImmune, the Supreme Court wrote about immediacy as a property of the declaratory judgment controversy itself. Deva and the Supreme Court used the same word, "immediacy," but in different contexts.

action against Deva on all the patents that are the subject of the declaratory judgment claims, has a real and imminent controversy with Deva over the issue of whether or not its proposed generic product would infringe these patents, if and when they came to market. As Teva has noted, Deva has not given any indication that, if its ANDA were approved, it would not proceed to market. Under MedImmune, this is more than sufficient to demonstrate that an actual controversy subject to judicial resolution exists between the parties, and that this Court has subject matter jurisdiction. Applying the principles set forth in MedImmune to the instant case, this Court concludes that a justiciable declaratory judgment controversy has arisen. The motion to dismiss the declaratory judgment claims for lack of subject matter jurisdiction will be denied.

As to the claims for infringement under 35 U.S.C. § 271(e)(2), Deva argues that this Court should apply the reasoning explained in an Opinion in another case, Teva Branded Pharm. Prod. R&D, Inc. v. Amneal Pharms. of New York, LLC, No. CV 23-20964 (SRC), 2024 WL 2923018, at *8 (D.N.J. June 10, 2024). In its supplementary brief, Teva argued, in effect, that this Court was going off on a tangent, and requested that, if this Court was going to connect the present jurisdictional question to the reasoning of Teva v Amneal, it should wait until the Federal Circuit has decided the pending appeal in that case. This request seems quite sensible, and, as to the motion to dismiss the Hatch-Waxman claims only, the Court will defer further consideration of the motion to dismiss until the appeal in Teva v Amneal has reached a final decision.

For these reasons,

IT IS on this 28th day of August, 2024

ORDERED that the motion to dismiss (Docket Entry No. 11), pursuant to Federal Rule of Civil Procedure 12(b)(1), by Defendant Deva, is **DENIED** in part and decision is

RESERVED in part; and it is further

ORDERED that, as to the motion to dismiss the claims for infringement under 35 U.S.C. § 271(e)(2), decision is **RESERVED** during the pendency of the appeal in Teva v Amneal; and it is further

ORDERED that, as to the motion to dismiss the declaratory judgment claims, the motion to dismiss is **DENIED.**

s/ Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.